

510(k) Submission, Gish CAPVRF Hardshell Venous Reservoir with GBS™ Coating

Gish Biomedical, Inc., Rancho Santa Margarita, CA 92688

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR part 807.92.

1. Company making the submission:

	Company:	or	Correspondent (contract):
Name:	Gish Biomedical, Inc.		Delphi Consulting Group
Address:	22942 Arroyo Vista Rancho Santa Margarita CA 92688-2600		11874 South Evelyn Circle Houston, TX 77071-3404
Telephone:	949-635-6240 voice 949-635-6294 fax		832-285-9423 voice 775-429-9524 fax
Contact:	Edward F. Waddell Director RA/QA		harvey@delphiconsulting.com J. Harvey Knauss Consultant

2. Device:

Proprietary Name:	Gish CAPVRF44 Hardshell Venous Reservoirs with GBS™ Coating
Common Name:	Cardiopulmonary Blood Reservoir
Classification Name:	Extracorporeal circuit blood defoamer Cardiopulmonary bypass blood reservoir

3. Predicate Devices:

Gish CAPVRF45 Hardshell Venous Reservoir, Gish Biomedical, Inc., K964973.

4. Classifications Names & Citations:

5. 21 CFR 870.4230, 21 CFR 870.4400, Extracorporeal circuit blood defoamer, Cardiopulmonary bypass blood reservoir, Cardiopulmonary Bypass, Class II, DTN, Cardiovascular.

6. Description:

The Gish CAPVRF44 Hardshell Venous Reservoirs are sterile, non-pyrogenic, single use, disposable, device designed for collection, storage and filtration of blood during cardiopulmonary bypass. The Gish CAPVRF44 has a clear polycarbonate shell and an internal defoamer filter cartridge. Venous drainage enters the 1/2" venous inlet where it is directed to the bottom of the device and passes through a 160 micron screen filter. Intrathoracic suctioned blood enters the top section of the defoamer/filter cartridge and passes through a defoamer sponge and 20 micron depth filter. The maximum venous flow rate is 8 lpm. The maximum cardiotomy flow rate is 4 lpm.

7. Indications for use:

The Gish CAPVRF44 Hardshell Venous Reservoirs are indicated for use during cardiopulmonary bypass surgery as a storage reservoir for gravity and augmented venous return blood and to filter and defoam intrathoracic suctioned blood prior to its return to the extracorporeal circuit at flow rates of one (1.0) to eight (8.0) liters per minute for periods up to six hours (6.0) hours. The Gish CAPVRF44 Hardshell Venous Reservoirs are also indicated for the collection and autotransfusion

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of the same patient's postoperative shed blood with the addition of the Postoperative Conversion Pack with water seal/manometer.

8. Contraindications:

This device is not designed, sold or intended for use except as indicated.

The Gish CAPVRF44 is contraindicated for use in blood transfusions when:

1. Protamine is administered in the operating room before the reservoir is removed from the extracorporeal circuit or any time the reservoir becomes contaminated with protamine.
2. Pulmonary, pericardial, mediastinal or systemic infection is present.
3. Gross contamination, malignancy, perforated intestine or lymphatic failure exists or is thought to exist.
4. Gross perforations of the chest wall/lung result in air leak.
5. The patient is returned to surgery for any reason.
6. The chest is open and vacuum is applied.
7. Vented chest tubes not incorporating vent flow regulation (such as a stopcock) are used..

For heparin coated devices, heparin has been reported, on rare occasions, to induce thrombocytopenia. Since patients undergoing cardiopulmonary bypass are routinely systemically heparinized, and although the amount of heparin contributed by this device is very small in comparison to the typical dose given, caution should be exercised when using this device in patients with known or suspected heparin sensitivity.

9. Comparison:

The Gish CAPVRF44 Hardshell Venous Reservoirs with GBS™ Coating has the same device characteristics as the predicate devices.

10. Test Data:

The Gish CAPVRF44 Hardshell Venous Reservoir with GBS™ Coating has been subjected to extensive safety, performance, and validations prior to release. Final testing for the systems includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies with applicable industry and safety standards.

11. Literature Review:

A review of literature pertaining to the safety and effectiveness has been conducted. Appropriate safeguards have been incorporated in the design of Gish CAPVRF44 Hardshell Venous Reservoirs with GBS™ Coating.

12. Conclusions:

The conclusion drawn from these tests is that Gish CAPVRF44 Hardshell Venous Reservoir with GBS™ Coating is equivalent in safety and efficacy to its predicate device the Gish CAPVRF45.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2003

Gish Biomedical, Inc.
c/o Mr. Edward Waddell
22942 Arroyo Vista
Rancho Santa Margarita, CA 92688-2600

Re: K030726

Gish CAPVRF44 Hardshell Venous Reservoirs with GBS™ Coating

Regulation Number: 870.4400

Regulation Name: Cardiopulmonary Bypass Blood Reservoir

Regulatory Class: Class II (two)

Product Code: DTN

Dated: March 5, 2003

Received: March 7, 2003

Dear Mr. Waddell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K K030726

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Indications for use:

The Gish CAPVRF44 Hardshell Venous Reservoirs are indicated for use during cardiopulmonary bypass surgery as a storage reservoir for gravity and augmented venous return blood and to filter and defoam intrathoracic suctioned blood prior to its return to the extracorporeal circuit at flow rates of one (1.0) to eight (8.0) liters per minute for periods up to six hours (6.0) hours. The Gish CAPVRF44 Hardshell Venous Reservoirs are also indicated for the collection and autotransfusion of the same patients post operative shed blood with the addition of the Postoperative Conversion Pack with water seal/manometer.

Prescription Device:

Federal Law (US) restricts this device to sale by or on the order of a physician.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

[Signature] for RDE
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K030726

(Optional Format 1-2-96)